Debbie Lumpkins telephoned Mr. Raybin and requested that the following item be submitted to Docket 74N-183H:

1. Statistical data for clinical handwash studies should be submitted to the Docket in an SAS transport file.

Mr. Raybin agreed to this request. General information was provided about the rationale for the request. Ms. Lumpkins referred Mr. Raybin to the FDA website for the Guidance addressing how to submit statistical data to the agency.

The conversation concluded cordially.



Food and Drug Administration Center for Drug Evaluation and Research Office of Drug Evaluation V

9672 °02 MAY 10 P1:27

FACSIMILE TRANSMITTAL SHEET

DATE: May 3, 2002		
To: Kip Raybin Company: International Laboratory Testing Corporation		From: Tia Frazier Debbie Lumpkins
		Division of Division of Over-the-Counter Drug Products
Fax number: RECIPIENT'S FAX NUMBER		Fax number: SENDER'S FAX NUMBER
Phone number: 954-893-1118		Phone number: 301-827-2271
Subject: Format for statistical submission	on to Docket 75N	-183H
Total no. of pages including cove	r: 1	
Comments:		
Document to be mailed:	□YES	⊠NO

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.

If you are not the addressee, or a person authorized to deliver this document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us immediately by telephone at (301) 827-2222. Thank you.

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:	5-7-02	
FROM:	Director Division of OTC Drug Products, HFD-560	
SUBJECT:	Material for Docket No. 75N-183H	
TO:	Dockets Management Branch, HFA-305	
	The attached material should be placed on public display under the above referenced Docket No.	
	This material should be cross-referenced to Comment No.	

Charles J. Ganley, M.D.

Attachment